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| ATTY. DOCKET NO. 02486.0069.NPUS01 | APPLICATION NO. 10/698,066 |
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| Cynthia B. Robinson, et al.        | -                          |
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| EXAMINER |     | DOCUMENT NUMBER | DATE      | NAME           | CLASS    | SUBCLASS                                       | FILING DATE |
| W        | 1.  | 4,254,129       | Mar. 1981 | Carr et al.    |          |  | •           |
|          | 2.  | 4,282,233       | Aug. 1981 | Vilani         |          |  |             |
| ,        | 3.  | 4,393,066       | Jul. 1983 | Garrett et al. |          |  |             |
|          | 4.  | 4,499,064       | Feb. 1985 | Shive          |          |  |             |
|          | 5.  | 4,525,358       | Jun. 1985 | Baltes et al.  |          |  |             |
|          | 6.  | 4,575,498       | Mar. 1986 | Holmes et al.  |          |  |             |
|          | 7.  | 4,628,052       | Dec. 1986 | Peat           |          |  |             |
|          | 8.  | 4,920,115       | Apr. 1990 | Nestler et al. |          |  |             |
|          | 9.  | 4,931,441       | Jun. 1990 | Lawrence       |          |  |             |
|          | 10. | 4,985,443       | Jan. 1991 | Montes         |          |  |             |
|          | 11. | 5,021,417       | Jun. 1991 | Prost          |          |  |             |
|          | 12. | 5,059,595       | Oct. 1991 | Le Grazie      |          |  |             |
|          | 13. | 5,077,284       | Dec. 1991 | Loria et al.   |          |  |             |
|          | 14. | 5,110,810       | May 1992  | Eich et al.    |          | ·  |             |
|          | 15. | 5,118,505       | Jun. 1992 | Költringer     |          |  |             |
|          | 16. | 5,162,198       | Nov. 1992 | Eich et al.    |          |  |             |
|          | 17. | 5,173,488       | Dec. 1992 | Haeger         |          |  |             |
|          | 18. | 5,177,076       | Jan. 1993 | Nijkerk et al. | <u> </u> |  |             |
|          | 19. | 5,266,312       | Nov. 1993 | Leung et al.   |          |  |             |
|          | 20. | 5,270,305       | Dec. 1993 | Palmer         |          |  |             |
|          | 21. | 5,347,005       | Sep. 1994 | Mueller et al  |          |  |             |
|          | 22. | 5,375,693       | Dec. 1994 | Woosley et al. |          |  |             |
| 1        | 23. | 5,407,684       | Apr. 1995 | Loria et al.   |          |  |             |

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PTO FORM 1449

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| October 29, 2003                   | 1614                       |

|   |     |              |           |                  |   |   | <br> |
|---|-----|--------------|-----------|------------------|---|---|------|
| U | 24. | 5,407,927    | Apr. 1995 | Morales et al.   |   |   |      |
|   | 25. | 5,489,581    | Feb. 1996 | Daynes et al.    |   |   |      |
|   | 26. | 5,527,789    | Jun. 1996 | Nyce             |   |   |      |
|   | 27. | 5,532,230    | Jul. 1996 | Daynes et al.    |   |   |      |
|   | 28. | 5,538,734    | Jul. 1996 | Le Grazie        |   |   |      |
|   | 29. | 5,578,610    | Nov. 1996 | D' Ambra         |   |   |      |
|   | 30. | 5,583,126    | Dec. 1996 | Daynes et al.    | • |   |      |
|   | 31. | 5,635,496    | Jun. 1997 | Daynes et al.    |   |   |      |
|   | 32. | 5,660,835    | Aug. 1997 | Nyce             |   | • |      |
|   | 33. | 5,686,438    | Nov. 1997 | Daynes et al.    |   |   |      |
|   | 34. | 5,703,063    | Dec. 1997 | Chasalow, et al. |   |   |      |
|   | 35. | 5,767,278    | Jun. 1998 | Gaeta et al.     |   |   |      |
| · | 36. | 5,811,418    | Sep. 1998 | Daynes et al.    |   |   |      |
|   | 37. | 5,859,000    | Jan. 1999 | Dowell et al.    |   |   |      |
|   | 38. | 5,861,391    | Jan. 1999 | Yen et al.       |   |   |      |
|   | 39. | 5,948,434    | Sep. 1999 | Labrie           |   |   |      |
| · | 40. | 6,087,351    | Jul. 2000 | Nyce             |   |   |      |
|   | 41. | 6,093,706    | Jul. 2000 | Zeligs           |   |   |      |
|   | 42. | 2002/0042401 | Apr. 2002 | Ferguson et al.  |   |   |      |
|   | 43. | 2003/0013772 | Jan. 2003 | Murphy et al.    |   |   |      |
|   | 44. | 2003/0138434 | Jul. 2003 | Campbell et al.  |   |   |      |
|   | 45. | 2003/0139331 | Jul. 2003 | Martin et al.    |   |   |      |
|   |     |              |           |                  |   |   |      |

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|           |                   | F  | OREIGN PA  | TENT DOCUMENTS                       |                | ·              |             |          |  |
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| 1         | 46.               | WO 93/16704  | ,  | PCT                                  |                |                |             |          |  |
|           | 47.0              | WO 96/16680  |  | PCT                                  |                |                |             | ļ        |  |
|           | 48:4              | WO 97/48367  |  | PCT                                  |                |                |             |          |  |
| ·         | 49.               | WO 98/03180  |  | PCT                                  |                |                |             | <u> </u> |  |
|           | 50.               | WO 00/54763  |  | PCT ·                                |                |                |             | · .      |  |
|           | 51.               | WO 01/015745   |  | PCT                                  |                |                | ٠.          |          |  |
|           | 52.               | WO 02/069955   |  | PCT                                  |                |                |             |          |  |
|           | 53.               | WO 02/85296  |  | PCT                                  |                |                |             |          |  |
|           | 54.               | WO 03/072572   | :<br>  | РСТ                                  |                |                |             |          |  |
|           | 55.               | WO 04/014993 A2                                      |  | PCT                                  |                |                |             | <u> </u> |  |
|           |                   | (Including   |  | REFERENCES<br>, Date, Pertinent Page | s, Etc.)       | -              |             |          |  |
|           | 56.<br>K          | Araneo et al., "Dehydroe<br>Thermal Injury", J. Surg |  |                                      | ive Dermal Iso | hemia Caus     | sed by      |          |  |
|           | 574               | Bonnett et al., "Dehydro<br>hypertension," PNAS 10   |  |                                      | and reverses o | chronic hypo   | xic pulmo   | nary     |  |
|           | 58.¥              | Budavari, The Merck Inc                              | Budavari, The Merck Index 11 <sup>th</sup> ed., 1989, pp. 660-661, monograph 4141.   |                                      |                |                |             |          |  |
|           | 59 <sub>7</sub> 0 |  | Coleridge et al., "Intravenous aminophylline confers no benefit in acute asthma treated with intravenous steroids and inhaled bronchodilators", Aust. N.Z. J. Med. 23:348-54 (1993). |                                      |                |                |             |          |  |
|           | 60.               | Dashtaki et al., " Dehydi<br>Smooth Muscle Prolifera |  |                                      |                |                | and Airwa   | у        |  |
|           | 61.10             | Dompeling et al., "Treat<br>Compliance and Inhaler   |  |                                      |                | c Bronchitis:  | Long Te     | rm       |  |
|           | 62.70             | Dunn, et al., "Dehydroep<br>N.Z. J, Med. 97(768):80  |  | ne sulphate concentrati              | ions in asthma | itic patients: | pilot stud  | ly,"     |  |
|           | 63.70             | Duplantier, et al., Novel potential of therapeutic   |  |                                      | treatment of   | asthma: stat   | tus and     |          |  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) | ATTY. DOCKET NO. APPLICATION NO. 10/698,066 |       |  |  |
|---|---|-------|--|--|
| PTO FORM 1449   | APPLICANT                                   |       |  |  |
|   | Cynthia B. Robinson, et a                   | I.    |  |  |
| •   | FILING DATE                                 | GROUP |  |  |
|   | October 29, 2003                            | 1614  |  |  |

|   | 64:4              | Dworski et al., "Conspectus: Inhaled Steroids in Asthma", Comprehensive Therapy, 18:3 (1992).   |
|---|-------------------|---|
|   | 65:7              | Feher et al., "Adrenocortical Function in Bronchial Asthma", Acta Medica Hungarica 40(2-3):125-32 (1983).   |
|   | 66.               | Fehér, et al., " Dehydroepiandrosterone Therapy of Patients with Corticosteroid Dependent Bronchial Asthma," Natl. Institute of Rheumatism and Physiotherapy, in XIII Congress of the European Academy of Allergology and Clinical Immunology, eds. (Saba, et al., Debrecen Hungary (1986). |
|   | 67. X             | Hampl et al., "Dehydroepiandrosterone sulphate reduces chronic hypoxic pulmonary hypertension in rats," J. Eur. Respir. 21:862-5 (2003).  |
|   | 68.               | Holzmann et al., "Therapy of Psoriasis with Dehydroepiandrosterone-Enanthate. II. Intramuscular Depot Application of 300 mg", Arch. Dermatol. Forsch. 247(1):23-8 (1973) (German with English Abstract).  |
|   | <sub>69</sub> ×   | Hummel et al., "Comparison of oral-steroid sparing by high-dose and low-dose inhaled steroid in maintenance treatment of severe asthma", <i>The Lancet</i> , 340(8834/8835):1483-7 (1992).  |
|   | 70 <sub>7</sub> C | Itagaki <i>et al.</i> , "Effect of Cortisol on the Release of Human Decidual", <i>Caplus</i> , 114875 (1991) (Japanese with English Abstract).  |
|   | 71.70             | Koó et al., "Our experiences with Dehydroepiandrosterone Therapy in Steroid-Dependent Intrinsic Bronchical Asthma", Orvosi Hetilap 128(38):1995-7 (1987) (Hungarian).   |
|   | 72.               | Koó et al., " Our experiences with Dehydroepiandrosterone Therapy in Steroid-Dependent Intrinsic Bronchical Asthma ", <i>Orvosi Hetilap</i> 128(38):1995-7 (1987) (English translation).  |
|   | 73.00             | Lejeune, "Pathogenesis of Mental Impairment in Trisomy 21", <i>Annales de Génétique</i> , 92:27643 (1996) (French with English Abstract).   |
| _ | 74.XO             | Mileva et al., "Androstenedione, DHEA sulfate, cortisol, aldosterone and testosterone in bronchial asthma patients", 07608054 (1990) (Russian with English Abstract).   |
|   | 75.               | Nakagawa, et al., "The Properties of Water of Crystallization of Sodium Prasterone Sulfate," Chem Pharm. Bull 29(5):1466-9 (1981)   |
|   | 76.%              | Nakagawa, et al., "The Grinding and Drying on the Solid State Stability of Sodium Prasterone Sulfate," Chem. Pharm. Bull 30(1):242-8 (1982)   |
|   | 77.               | Pashko et al., "Inhibition of 7,12-dimethylbenz(a)anthracene-induced Skin Papillomas and Carcinomas by Dehydroepiandrosterone and 3-beta-methylandrost-5-en-17-one in mice", Cancer Res. 45(1):164-6 (1985).  |
|   | 78. 7             | Peeters et al., "Differences in Purine Metabolism in Patients with Down's Syndrome", J. Intellect. Diabil. Res. 37:471 (1993). Abstract.  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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|   | APPLICANT                                   |       |  |  |
|   | Cynthia B. Robinson, et al.                 |       |  |  |
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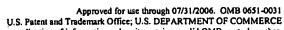
| ·                     | ·   |
|-----------------------|---|
| 79.<br>-£             | Reed, "Aerosol Steroids as Primary Treatment of Mild Asthma", New England J. Med., 325(6):425-6 (1991).   |
| 80.                   | Rowe et al., "Effectiveness of Steroid Therapy in Acute Exacerbations of Asthma: A Meta-analysis", Amer. J. Emergency Med., 10(4):301-10 (1992).  |
| 81                    | Sasaki et al., "Cervical Ripening with Dehydroepiandrosterone Sulphate", Br. J. Obstet. Gynaecol. 89(3):195-8, (1982).  |
| 82. <sub>C</sub>      | Sciarra et al., "Aerosols", Remington's Pharmaceutical Sciences, 18 <sup>th</sup> ed. (1990), Eds. Gennaro et al., pp. 1873-5 and 1694-1712.  |
| 83.7                  | Sharma et al., "Screening of potential chemopreventive agents using biochemical markers of carcinogenesis", Cancer Res. 54(22):5848-55 (1994).  |
| 84.                   | Shomali, "The Use of Anti-Aging Hormones. Melatonin. Growth Hormone, Testosterone, and Dehydroepiandrosterone: Consumer Enthusiasm for Unproven Therapies", <i>Md. Med. J.</i> 46(4):181-6 (1997).  |
| 85.7                  | Sonka et al., "Gout and Dehydroepiandrosterone: 3. DHEA Administration", Endokrynologia Polska 24(3):209-18 (1973).   |
| 86.                   | Sur et al., "Double-blind trial pyroxidine (vitamin B6) in the treatment of steroid-dependent asthma", <i>Ann. Allergy</i> , 70:147-52 (1993).  |
| 87.8                  | Schwartz et al., "Inhibition of 7,12-dimethylbenz[a]anthracene- and urethan-induced lung tumor formation in A/J mice by long-term treatment with dehydroepiandrosterone," Carcinogenesis 2(12):1335-7 (1981)                              |
| 88)                   | Van de Graaf et al., "Respiratory Membrane Permeability and Bronchial Hyperreactivity in Patients with Stable Asthma: Effects of Therapy with Inhaled Steroids", Bronchial Asthma and Respiratory Membrane Permeability 143:362-8 (1991). |
| <b>89.</b> \(\infty\) | Van Vollenhoven et al., "Dehydroepiandrosterone in SLE. Results of a Double-Blind, Placebo-Controlled, Randomized Clinical Trial.", Arthntis Rheum. 38(12): 1826-31 (1995).   |
| 90.7                  | Wolkowitz et al., "Dehydroepiandrosterone Treatment of Depression", Biol. Psychiatry 41(3):311-8. (1997).   |

Not considered - not provided by The applicant

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| 1.1                   |                          | US-2003/0216329   | 11-20-2003                     | Robinson et al.                                    |   |
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